902 KAR 20:275. Freestanding or mobile technology.

RELATES TO: KRS 211.842 – 211.852, 216B.010-216B.170, 216B.990, 29 C.F.R. 1910.1030(d)(2)(vii), 45 C.F.R. 160, 164, 42 U.S.C. 263b(f)(1)(G), 1320d

STATUTORY AUTHORITY: KRS 216B.042

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, which includes establishing licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services. This administrative regulation establishes the minimum licensure requirements for the operation of and services provided by a freestanding or mobile technology unit.

Section 1. Definitions. (1) "License" means an authorization issued by the cabinet for the purpose of operating a freestanding or mobile technology unit.

(2) "Magnetic resonance imaging" or "MRI" means a diagnostic imaging modality that utilizes magnetic resonance, an interaction between atoms and electromagnetic fields, to project images of internal body structures.

(3) "Positron emission tomography scanning" or "PET scanning" means a procedure that allows the study of metabolic processes, such as oxygen consumption and utilization of glucose and fatty acids, by capturing images of cellular activity or metabolism by tracking the movement of radioactive tracers throughout the body.

Section 2. Scope of Operations. In accordance with KRS 216B.020(3)(c) and (f), a freestanding or mobile technology unit that provides diagnostic or therapeutic equipment or procedures, i.e., MRI, PET scanning, cardiac catheterization, or megavoltage radiation therapy services, shall be licensed by the cabinet.

Section 3. Administration. (1) Licensee.

(a) The licensee shall be legally responsible for:

1. All activities of the licensed freestanding or mobile technology unit; and

2. Compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the freestanding or mobile technology unit.

(b) The licensee shall:

1. Establish lines of authority; and

2. Designate an administrator who shall be principally responsible for the daily operation of the freestanding or mobile technology unit.

(2) Policies and procedures.

(a) The licensee shall develop and implement policies and procedures that address:

1. Care, treatment, procedures, services, and qualifications of personnel involved in the delivery of services; and

2. The operation of equipment.

(b) The policies and procedures shall be revised as needed to accurately reflect actual operations.

(c) The licensee shall establish a time period for review of all policies and procedures.

(d) The policies and procedures shall be accessible either by hard copy or electronically.

(3) Personnel.

(a) The licensee shall employ a sufficient number of qualified staff to operate equipment in a manner that safely and effectively meets the needs and condition of the patients.

(b) Staffing numbers and training shall:

1. Meet the recommendations of the equipment manufacturers;

2. Adhere to current professional organizational standards; and

3. Comply with all local, state, and federal laws.

(c) Additional staff members shall be provided if the licensee or cabinet determines that the staff on duty is inadequate to effectively and safely operate the equipment.

(d) Each staff member operating or maintaining equipment shall be assigned duties and responsibilities in accordance with the individual's capability.

(e) Assigned duties shall be:

1. In writing; and

2. Reviewed on an annual basis by the staff member and supervisor.

(f) A medical director:

1. Shall be a physician who is responsible for the quality of medical equipment services provided to patients; and

2. May serve as the administrator as described by subsection (1)(b) of this section.

(4) Personnel records. The licensee shall maintain current personnel records for each employee that shall contain the following:

(a) Name, address, and Social Security number;

(b) Evidence of current registration, certification, or professional licensure;

(c) Documentation of training and experience;

(d) Performance evaluations; and

(e) Record of pre-employment and regular health exams related to employment.

(5) In-service training. Staff shall attend training programs relating to their respective job activities. The training programs shall include:

(a) Thorough job orientation for new employees; and

(b) In-service training programs, emphasizing competence and professionalism necessary for effective health care.

(6) Health assessment. All staff members who have contact with patients shall:

(a) Within twelve (12) months prior to initial patient contact, have a health assessment; and

(b) Comply with the tuberculosis (TB) testing requirements established in 902 KAR 20:205.

(7) Medical records.

(a) The licensee shall maintain medical records that contain the following:

1. Medical and social history relevant to each service provided, including data obtained from other providers;

2. Physician's orders if an order is required for a specific diagnostic service;

3. Description of each medical visit or contact, including a description of the:

a. Condition or reason for the visit or contact;

b. Assessment;

c. Diagnosis;

d. Services provided;

e. If applicable, medications and treatments prescribed; and

f. Disposition made;

4. Reports of all physical examinations, laboratory, x-ray, and other test findings related to each service provided; and

5. Documentation of all referrals made, including reason for referral and to whom patient was referred.

(b) Ownership.

1. Medical records shall be the property of the freestanding or mobile technology unit.

2. The original medical record shall not be removed except by court order.

3. Copies of a medical record or portions of the record may be used and disclosed, in ac-

cordance with the requirements established in this subsection.

(c) Confidentiality and security: use and disclosure.

1. The freestanding or mobile technology unit shall maintain the confidentiality and security of medical records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, as amended, including the security requirements mandated by subparts A and C of 45 C.F.R. Part 164, or as provided by applicable federal or state law.

2. The freestanding or mobile technology unit may use and disclose medical records. Use and disclosure shall be as established or required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, or as established in this administrative regulation.

3. This administrative regulation shall not forbid the freestanding or mobile technology unit from establishing higher levels of confidentiality and security than required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164.

(d) Transfer of records. The licensee shall:

1. Establish procedures to assist in continuity of care if the patient moves to another source of care; and

2. Upon proper release, transfer medical records or an abstract, if requested.

(e) Retention of records. After the patient's death or discharge, the completed medical record shall be placed in an inactive file and retained for:

1. Six (6) years; or

2. If a minor, three (3) years after the patient reaches the age of majority under state law, whichever is the longest.

(f) Radiology records shall be retained in accordance with 42 U.S.C. 263b(f)(1)(G).

(g) A specific location shall be designated by the licensee for the maintenance and storage of the unit's medical records.

(h) The licensee shall ensure safe storage of medical records if the unit ceases to operate because of disaster or for any other reason.

(i) The licensee shall safeguard the record and its content against loss, defacement, and tampering.

Section 4. Reporting; Incidents and Accidents. (1) A record of each incident or accident occurring in the equipment location area involving patients or staff members shall be retained for a period of two (2) years from the date of the incident or accident.

(2) A serious incident, accident, or medical condition as established in subsection (3) of this section and any illness resulting in death or inpatient hospitalization shall be reported via telephone to the next-of-kin or responsible party immediately and in writing to the Office of Inspector General within ten (10) days of the occurrence.

(3) A serious incident, accident, or medical condition shall include any of the following:

(a) Major permanent loss of function;

(b) A procedure on the wrong patient or wrong body part;

(c) Fractures of major limbs or joints;

(d) Severe burns, lacerations, or hematomas; and

(e) Actual or suspected abuse or mistreatment of patients.

(4) Reports made to the Office of Inspector General shall contain:

(a) Facility name;

(b) Patient age and sex;

(c) Date of incident or accident;

(d) Location;

(e) Extent or type of injury; and

(f) Means of treatment, e.g., hospitalization.

(5) A significant medication error or significant adverse medication reaction as established in subsection (6) of this section that requires intervention shall be reported immediately to the:

(a) Patient, next-of-kin, or responsible party;

(b) Prescriber;

(c) Supervising staff member; and

(d) Administrator.

(6) A significant medication error or significant adverse medication reaction shall include any event that is unintended and undesirable, including an unexpected effect of a prescribed medication or of a medication error that:

(a) Requires discontinuing a medication or modifying the dose;

(b) Requires hospitalization;

(c) Results in disability;

(d) Requires treatment with a prescription medication;

(e) Results in cognitive deterioration or impairment;

(f) Is life-threatening; or

(g) Results in death.

(7) Changes in the patient's condition, to the extent that a major cardiac event or other serious health concern is evident, shall be reported immediately to the:

(a) Attending physician;

(b) Next-of-kin or responsible party; and

(c) On-site manager.

Section 5. Provision of Services. (1) Care, treatment, procedures, or services shall be provided, given, or performed effectively and safely in accordance with an order from a physician or other licensed health care practitioner acting within his or her scope of practice.

(2) Precautions shall be taken for a patient who:

(a) Has a special condition, such as pacemaker, pregnancy, or Alzheimer's disease; or

(b) May be susceptible to deleterious effects as a result of the treatment.

(3) If a patient or potential patient has a communicable disease, a physician or other licensedhealth care practitioner acting within his or her scope of practice shall ensure that:

(a) Adequate care is provided to prevent the spread of the disease; and

(b) The staff members are adequately trained and qualified to:

1. Manage the patient; or

2. Transfer the patient to an appropriate facility, if necessary.

(4) If the licensee engages a source to provide services normally provided by the staff, e.g., staffing, training, equipment maintenance, there shall be a written agreement with the source that describes:

(a) How and when the services are to be provided;

(b) The exact services to be provided; and

(c) A statement that these services are to be provided by qualified individuals.

(5) A current listing of all types of treatment and procedures offered shall be available.

(6) Anesthesia services. After the administration of a general anesthetic, a patient shall be attended by a physician until the patient may be safely placed under post-operative or procedure supervision by the nursing staff who shall then attend the patient until:

(a) The patient has regained full consciousness; or

(b) The effects of the anesthetic have sufficiently subsided for the patient to be able to summon aid if needed.

(7) Laboratory services.

(a) If required in connection with the treatment or procedure performed, laboratory services shall be provided directly or through an arrangement with a licensed laboratory.

(b) Laboratory supplies shall not be expired.

(8) Megavoltage radiation therapy services. A licensee that provides megavoltage radiation therapy services shall comply with the requirements of this subsection.

(a) Sufficient personnel shall be present to supervise and perform the services provided by the facility, including at least one (1):

1. Certified radiation operator; or

2. Physician with specialized training and experience to perform the scope of radiation therapy services provided.

(b) The licensee shall be currently licensed or registered pursuant to KRS 211.842 to 211.852.

(c) There shall be written policies and procedures governing radiologic services and administrative routines that support sound radiologic practices.

(d) Reports of interpretations shall be written or dictated and signed by the radiologist or physician.

(e) The use of all x-ray apparatus shall be limited to certified radiation operators or physicians.

(f) Only a certified radiation operator or physician may apply or remove radium element, its disintegration products, and radioactive isotopes.

(g) Proper safety precautions shall be maintained against fire, explosion, electrical, and radiation hazards.

(9) Adverse conditions.

(a) If a patient experiences any adverse condition or complication during or after the performance of the treatment or procedure, the patient shall remain at the equipment location until the condition or complication is eliminated, as determined by the physician, and the patient is stabilized.

(b) A patient who requires care beyond the capability of the equipment or staff shall be transferred to an appropriate facility.

(10) Patient instruction. Written instructions, if applicable, shall be issued to each patient upon discharge, including:

(a) Signs and symptoms of possible complications;

(b) Telephone number of the location of the equipment, the attending physician, or other knowledgeable professional staff member, if any complication occurs or questions arise;

(c) An emergency telephone number if any complication occurs;

(d) Limitations regarding activities or foods; and

(e) Date for follow-up or return visit, if applicable.

Section 6. Rights and Assurances. (1) The licensee shall develop and post in a conspicuous place in a public area a grievance or complaint procedure to be exercised on behalf of the patients, including the address and phone number of the Office of Inspector General.

(2) Care, treatment, procedures, and services provided, and the charges for each shall be delineated in writing.

(3) Patients shall be made aware of all charges and services, as verified by the signature of the patient or responsible party.

(4) Storage shall be provided to protect a patient's personal belongings.

(5) Patient rights shall be guaranteed, prominently displayed, and the patient shall be informed of these rights, including:

(a) The care, treatment, procedures, and services to be provided;

(b) Informed consent for care, treatment, procedures, and services;
(c) Respect for the patient's property;
(d) Freedom from mental and physical abuse and exploitation;
(e) Privacy while being treated and receiving care;
(f) Respect and dignity in receiving care, treatment, procedures, and services;
(g) The consequences of refusal of the treatment or procedure;
(h) Refusal of experimental treatment and drugs; and
(i) Confidentiality and privacy of records.
(6) Except in an emergency, documentation regarding informed consent shall be properly executed prior to the treatment or procedure.

Section 7. Medication. (1) Medication orders.
(a) Medications, including oxygen, shall be administered to patients only upon the order of a physician or other licensed health care practitioner acting within his or her scope of practice.
(b) All orders, including verbal, shall be:
1. Received only by a licensed health care practitioner acting within his or her scope of practice; and
2. Authenticated and dated by a physician or other licensed health care practitioner acting within his or her scope of practice pursuant to the licensee’s policies and procedures, but no later than seventy-two (72) hours after the order is given.
(c) Verbal orders received shall include:
1. The time of receipt of the order;
2. Description of the order; and
3. Identification of the physician or other licensed health care practitioner and the individual receiving the order.
(2) Administering medication.
(a) Each medication dose administered shall be properly recorded in the patient's record as the medication is administered.
(b) The medication administration record shall include the:
1. Name of the medication;
2. Dosage;
3. Mode of administration;
4. Date;
5. Time; and
6. Signature of the individual administering the medication.
(c) Initials may be utilized in lieu of a signature and identification of the individual's initials shall be located within the record.
(3) Medication storage.
(a) Medications shall be stored:
1. Under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, safety, and security; and
2. Safeguarded to prevent access by unauthorized persons.
(b) Expired or discontinued medications shall not be stored with current medications.
(c) Storage areas shall:
1. Be of sufficient size for clean and orderly storage;
2. Be locked if not under direct observation by a licensed health care practitioner; and
3. Not be located near sources of heat, humidity, or other hazards that may negatively impact medication effectiveness or shelf-life.
(d)1. Medications requiring refrigeration shall be stored in a refrigerator at the temperature

established by the U.S. Pharmacopeia (36 - 46 degrees F.).

2. Food and drinks and laboratory specimens shall not be stored in the same refrigerator in which medications and biologicals are stored.

3. Blood and blood products may be stored in the same refrigerator with medications and biologicals if stored in a separate compartment from the medications and biologicals.

(e) Medications shall be stored:

1. Separately from poisonous substances, blood, or body fluids;

2. In a manner that provides for separation between oral and topical medications; and

3. Separately from food.

(4) Disposition of medications.

(a) Medications shall not be retained in stock after the expiration date on the label.

(b) Contaminated or deteriorated medications shall not be maintained.

Section 8. Emergency procedures and disaster preparedness. (1) Emergency services.

(a) Appropriate equipment and services shall be provided to render emergency resuscitative and life-support procedures pending transfer to a hospital, if necessary.

(b) The licensee shall make arrangements for obtaining blood and blood products to meet emergency situations.

(2) Disaster preparedness. The licensee shall establish plans, based on equipment and staff capabilities, to meet its responsibilities for providing emergency care.

(3) Emergency call numbers.

(a) In addition to access to "911," emergency call data shall:

1. Be immediately available; and

2. Include the telephone numbers of:

a. Fire and police departments;

b. Ambulance service; and

c. The Poison Control Center.

(b) Other emergency call information shall be available, including the names, addresses, and telephone numbers of staff members to be notified in case of emergency.

Section 9. Equipment Maintenance. (1) Equipment utilized for providing treatment or procedures, including its component parts, shall be properly maintained to perform the functions for which it is designed.

(2) Equipment.

(a) Equipment used in the provision of care, treatment, procedures, and services shall:

1. Meet appropriate specifications and calibrations; and

2. Be monitored and operated in accordance with the manufacturer's guidelines.

(b) Records shall be maintained to indicate all testing and maintenance.

(c) If equipment for the administration of anesthesia is utilized, it shall be readily available, clean or sterile, and operating properly.

1. Anesthesia apparatus shall be equipped with a device to measure the oxygen component of the gas being inhaled by the patient.

2. The device shall emit audible and visual alarms if the proportion of oxygen falls below a safe level.

3. A record of the inspections made prior to each use of the anesthesia equipment and a record of all service and repair performed on all anesthesia machines, vaporizers, and ventilators shall be maintained and retained:

a. For a minimum of two (2) years from the date of the inspection, service, or repair or

b. Until the next Office of Inspector General survey.

Section 10. Physical Environment. (1) Accessibility. A licensee shall meet requirements for making buildings and facilities accessible to and usable by individuals with physical disabilities pursuant to federal, state, and local laws.

(2) Fire safety. A fixed-site location shall be approved by the state Fire Marshal's office before licensure is granted by the cabinet.

(3) Environment. The building in which equipment is utilized shall be planned, designed, and equipped to provide and promote the health, safety, and well-being of each patient.

(4) Infection control. The licensee shall develop written infection control policies that are consistent with Centers for Disease Control guidelines, available at www.cdc.gov/ncidod/dhqp/guidelines.html, and shall include:

(a) Prevention of disease transmission to and from patients, visitors, and employees, including:

1. Universal blood and body fluid precautions;

2. Precautions against airborne transmittal of infections; and

3. Work restrictions for employees with infectious diseases; and

(b) Cleaning, disinfection, and sterilization methods used for equipment and the environment.

(5) Housekeeping and maintenance.

(a) The equipment location shall be neat, uncluttered, clean, and free of vermin and offensive odors.

(b) Hazardous cleaning solutions, compounds, and substances shall be:

1. Labeled;

2. Stored in closed metal containers;

3. Kept separate from other cleaning materials; and

4. Kept in a locked storage area.

(c) Garbage and trash:

1. Shall be removed from the premises regularly; and

2. Containers shall be cleaned regularly as needed.

(d) A licensee shall establish and maintain a written policy for the handling and disposal of wastes, including any infectious, pathological, and contaminated wastes, which shall include the following:

1. Sharp wastes shall be segregated from other wastes and placed in puncture-resistant containers immediately after use;

2. A needle or other contaminated sharp shall not be recapped, purposely bent, broken, or otherwise manipulated by hand as a means of disposal, except as permitted by the Centers for Disease Control and Prevention and the Occupational Safety and Health Administration guidelines at 29 C.F.R. 1910.1030(d)(2)(vii);

3. A sharp waste container shall be incinerated on or off-site or rendered nonhazardous; and

4. Any nondisposable sharps shall be placed in a hard walled container for transport to a processing area for decontamination.

(e) Disposable waste shall be:

1. Placed in a suitable bag or closed container so as to prevent leakage or spillage; and

2. Handled, stored, and disposed of in such a way as to minimize direct exposure of personnel or patients to waste materials.

(f) An incinerator used for the disposal of waste shall be in compliance with 401 KAR 59:020 or 401 KAR 61:010.

Section 11. Quality assurance program. A licensee shall have a written, implemented quality assurance program that:

(1) Includes effective mechanisms for reviewing and evaluating patient care; and

(2) Provides for appropriate responses to findings.

Section 12. Mobile Technology Units. (1) All mobile technology units, e.g., self-contained vans or tractor trailers, that transport equipment from one (1) host site to another, shall meet the current standards of this administrative regulation and of the local, state, and federal Departments of Transportation for the permitting and safe operation of the vehicle.

(2) A mobile cardiac catheterization laboratory shall only provide services on the campus of a host hospital that has emergency medical and intensive coronary care services.

(3) A procedure shall not be performed on a patient in a mobile cardiac catheterization laboratory if any of the following are present:

(a) Recent myocardial infarction (within ten (10) days or less);

(b) Uncontrolled arrhythmias;

(c) Severe uncontrolled congestive heart failure;

(d) Current hospitalization with highly unstable angina; or

(e) The patient is under eighteen (18) years of age. (23 Ky.R. 2645; 2999; eff. 1-15-1997; TAm eff. 3-11-2011; TAm eff. 12-10-2012; 42 Ky.R.2275, 2735; eff. 6-3-2016; 45 Ky.R. 485, 1031; eff. 11-2-2018.)